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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,581	04/07/2004	Mark E. Deem	37531-501C02 (17315-00200)	8576
78169 7590 01/27/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, PC ATTN: PATENT INTAKE CUSTOMER NO. [EVALVE] ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 01/27/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,581	Applicant(s) DEEM ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>NPL reference</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 September 2008 has been entered.

Response to Arguments

Applicant's arguments filed 8 September 2008 have been fully considered but they are not persuasive.

Applicant argues that it would be unlikely, if not impossible, to perform both the orifice repair and the annuloplasty of Maisano with the same catheter because the two procedures were performed in separate procedures. This argument is not persuasive because it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-9, 21, 23, 25, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over F. Maisano et al (European Journal of Cardio-thoracic Surgery 13 (1998) 240-246) in view of Aldrich et al. (US Patent 6,355,030).

Claims 1-3, 5-9, 21, 23, 25, 26: Maisano teaches that it is known to apply an annuloplasty ring the annulus of a valve and also apply sutures to adjacent leaflets (last partial paragraph on page 241 to first full paragraph on page 242).

Maisano does not teach performing the procedure percutaneously.

Aldrich'030 teaches that it is well known to repair heart valves percutaneously (column 15, line 57 to column 16, line 4) because it is less risky for the patient and requires less recovery time. It would have been obvious to one of ordinary skill in the art to perform the procedure of Maisano percutaneously so that it too has this advantage.

Claims 4, 10, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maisano in view of Aldrich, as applied to Claims 1 and 21, in further view of Carpentier et al. (US Patent 5,593,435).

Claim 4, 10, 24: Maisano teaches accessing the valve through the left atrium (last full paragraph on page 241), but Maisano does not teach attaching the ring on the atrial side.

Carpentier teaches that it is known to access the left atrium by crossing the interatrial septum in order to perform maintenance on an annuloplasty ring, which is attached on the atrial side (column 4, lines 43-55; Figure 4). If performing the deployment percutaneously, as discussed by Maisano in view of Aldrich, it would be obvious to use the procedure outlined by Carpentier because the technique for percutaneously accessing the valve through the atrial side was part of the ordinary capabilities of a person of ordinary skill in the art in view of the teaching of the technique for improvement in other situations.

Claims 1-3, 5-9, 11-17, 19, 21, 23, 25, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over G Noera et al ("Tricuspid Valve Incompetence Caused by Nonpenetrating Thoracic Trauma", *Annals of Thoracic Surgery* 51(2) (1991) p 320-22) in view of Aldrich et al. (US Patent 6,355,030).

Claims 1-3, 5-9, 11-17, 19, 21, 23, 25, 26: Noera teaches that it is known to apply an annuloplasty ring the annulus of a valve and also apply sutures to adjacent leaflets (page 320, first paragraph in the second column). Noera does not teach performing the procedure percutaneously.

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Aldrich'030 teaches that it is well known to repair heart valves percutaneously (column 15, line 57 to column 16, line 4) because it is less risky for the patient and requires less recovery time. It would have been obvious to one of ordinary skill in the art to perform the procedure of Noera percutaneously so that it too has this advantage.

Claims 4, 10, 18, 20, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noera in view of Aldrich, as applied to Claims 1, 11, and 21, in further view of Carpentier et al. (US Patent 5,593,435).

Claim 4, 10, 18, 20, 24: Noera does not teach attaching the ring on the atrial side.

Carpentier teaches that it is known to access the left atrium by crossing the interatrial septum in order to perform maintenance on an annuloplasty ring, which is attached on the atrial side (column 4, lines 43-55; Figure 4). If performing the deployment percutaneously, as discussed by Noera in view of Aldrich, it would be obvious to use the procedure outlined by Carpentier because the technique for percutaneously accessing the valve through the atrial side was part of the ordinary capabilities of a person of ordinary skill in the art in view of the teaching of the technique for improvement in other situations.

Claims 27-29 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noera in view of Aldrich and in further view of Carpentier et al. (US Patent 5,593,435).

Claim 27-29, 31-35: Noera teaches that it is known to apply an annuloplasty ring the annulus of a valve and also apply sutures to adjacent leaflets (page 320, first

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paragraph in the second column). Noera does not teach performing the procedure percutaneously.

Aldrich'030 teaches that it is well known to repair heart valves percutaneously (column 15, line 57 to column 16, line 4) because it is less risky for the patient and requires less recovery time. It would have been obvious to one of ordinary skill in the art to perform the procedure of Noera percutaneously so that it too has this advantage.

Also, Noera does not teach attaching the ring on the atrial side.

Carpentier teaches that it is known to access the left atrium by crossing the interatrial septum in order to perform maintenance on an annuloplasty ring, which is attached on the atrial side (column 4, lines 43-55; Figure 4). If performing the deployment percutaneously, as discussed by Noera in view of Aldrich, it would be obvious to use the procedure outlined by Carpentier because the technique for percutaneously accessing the valve through the atrial side was part of the ordinary capabilities of a person of ordinary skill in the art in view of the teaching of the technique for improvement in other situations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773